PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

G.E. EHRLICH (1995) LTD.
11 MENACHEM BEGIN STREET
RAMAT GAN, ISRAEL 52 521

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference 29953	Date of mailing (*day/month/year*) 03 AUG 2006 **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/IL05/01173	09 November 2005 (09.11.2005)	01 June 2005 (01.06.2005)

International Patent Classification (IPC) or both national classification and IPC

IPC: A61K 49/00(2006.01)
USPC: 424/9.1

Applicant

SPECTRUM DYNAMICS (ISRAEL) LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☒ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	03 July 2006 (03.07.2006)	Valerie Bell-Harris D. L. Jones Telephone No. ((571) 272-1600

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 7-1025

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international search *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 7-1025 are so unclear that no meaningful opinion could be formed *(specify)*:

Please See Continuation Sheet

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☐ no international search report has been established for said claims Nos. _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 5 and 6	YES
	Claims 1-4	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-6	NO
Industrial applicability (IA)	Claims 1-6	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 5 and 6 meet the criteria set out in PCT Article 33(2) because the prior art does not teach the claim limitations as written.

Claims 1-4 lack novelty under PCT Article 33(2) as being anticipated by Contag et al (US Patent No. 6,638,752).

Contag et al disclose biodetectors targeted to specific ligands. The biodetectors are used for detecting and quantifying molecules in liquid, gas, or matrices. The method involves biodetectors comprising a molecular switching mechanism to express a reporter gene upon interaction with target substances. For example, imaging of the light emitting biodetector entities may involve the use of a photodetector. If necessary, localization of the signal may be determined by integrating photon emission until and image is constructed. Once a photon emission image is generated, it is typically superimposed on a normal reflected light image of the subject to provide a frame of reference for the source of the emitted photons. Such a composite image is then analyzed to determine the location and/or amount of a target in the subject. Simple quantitation of the numbers of photons emitted from a sample indicate the concentration of the light-emitting reporter. The number of photons would therefore be proportional to the amount of targeted ligand that a specific detector is sensing. Without the constraints imposed by the need for an image, detectors may be place in very close proximity to the light emitting biodetectors; thus, optimizing the optical detection and sensitivity of the assay. Microchannel plate intensifiers may be used in such a configuration resulting in single photon detection (see column 8, lines 28-68; column 9, lines 25-54; column 16, lines 13-52). The signals generated by photodetector devices which count photons need to be processed by an image processor in order to construct an image which can be, for example, displayed on a monitor or printed on a video printer. Such image processors are typically sold as part of systems which include the sensitive photon counting cameral. The image processors are usually connected to a personal computed (column 17, lines 28-46). The biodetectors may be used to diagnose diseases, detect clinically relevant substances, detect environmental contaminants, and detect food contaminants (column 18, line 28 through column 19, line 54). Thus, both Applicant and Contag et al disclose a method of radioactive emission measures of a structure wherein radioactive emission measurement of a body are determined; radioactive emission measurements are analyzed; and additional views for measurement are analyzed.

Claims 5 and 6 lack an inventive step under PCT Article 33(3) as being obvious over Contag et al (US Patent No. 6,638,752). Contag et al (see discussion above) fail to specifically state that the additional views comprising determining that a photon count at a given view yields a measurement error below a specified value. However, it would have been obvious to one of ordinary skill at the time the invention was made that the additional views would be analyzed for error below a specified value because a skilled practitioner in the art would recognize that the duplicate images at specified conditions would enable one to determine the standard of deviation and mean value between the images.

Claims 1-6 meet the criteria set out in PCT Article 33 (4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

Section III. Non-establishment of opinion (description/claims/drawings unclear)
In the claims of the instant invention, the voluminous possible combinations make it virtually impossible to determine the full scope and complete meaning of the claimed subject matter. In particular, the claims are directed to a method of radioactive emission measurements of a body structure; a measurement unit for performing radioactive emission measurements of a body structure; a method of measuring kinetic parameters of a radiopharmaceutical in a body; a method of measuring kinetic parameters of a radiopharmaceutical in an organ; a drug formulation; a diagnositic kit; a method of imaging tissue; a method of obtaining image data; an apparatus for storing multidimensional imaging in a plurality of voxels; a method of assigning characteristics to a three dimensional imaging scan containing kinetic parameters; a pharmaceutical substance, and so forth. As a result, since the various components necessary to make/use each and every invention set forth in the instant application cannot be determined, it is unclear for what invention/inventions protection is sought. Thus, the claims as written cannot be regarded as being a concise description and as such do not comply with the requirements of PCT Article 6. Furthermore, it should be noted that due to the unlimited number of possible component combinations, it is impossible to perform a meaningful and timely search of the invention. Therefore, a search was conducted on the first discernible invention which has the following limitations as found in claims 1-6: a method having the limitation of independent claim 1 wherein (a) the views is associated with viewing parameters relating to the detector unit location; and (b) the analyzing step comprises determining that a photon count at a given view yields a measurement error below a specified error value which comprises extending a duration of a current view to obtain a required error rate.